PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Baldwins
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NEW ZEALAND

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *day/month/year*	6 OCT 2004
Applicant's or agent's file reference JP802458/142	**IMPORTANT NOTIFICATION**

International Application No.	International Filing Date	Priority Date
PCT/NZ2003/000116	10 June 2003	10 June 2002

Applicant

KERATEC LIMITED and UNIVERSITY OF OTAGO

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	ISOBEL TYSON Telephone No. (02) 6283 2281

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JP802458/142	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/NZ2003/000116	International Filing Date *(day/month/year)* 10 June 2003	Priority Date *(day/month/year)* 10 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl.[7] A61L 27/22, 27/46, 27/56, C08H 1/06, C08L 89/04, C08K 3/32		
Applicant KERATEC LIMITED and UNIVERSITY OF OTAGO		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [X] Certain observations on the international application

Date of submission of the demand	Date of completion of the report
12 December 2003	1 October 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ISOBEL TYSON Telephone No. (02) 6283 2281

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NZ2003/000116

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1-19,** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [X] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **20-23,** received on **29 March 2004** with the letter of **29 March 2004**
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-42**	**YES**
	Claims	**NO**
Inventive step (IS)	Claims **1-42**	**YES**
	Claims	**NO**
Industrial applicability (IA)	Claims **1-42**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

This International Preliminary Examination Report is based on the following documents which were identified in the International Search Report:

D1 = WO 1999/026570 A
D2 = WO 1999/019005 A
D3 = WO 2000/041739 A
D4 = US 2002013408 A
D5 = US 2001018614 A
D6 = US 5972385 A
D7 = US 2002183858 A
D8 = US 2003039676 A
D9 = JP 63229058 A
D10 = FR 2687577 A

NOVELTY (N) and INVENTIVE STEP (IS):

None of these documents disclose or teach towards the present claimed invention of Claims 1-42. These claims are therefore considered novel and inventive in light of these documents.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

New Claim 34 is not clear with regard to its appendency. In its original form this claim was appended to claims 31-33. Now, it is appended to claims 30-33. In light of the changes to the claim numbers due to amendment, it appears the appendency to new claim 34 should be to claims 30-*32*.

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CLAIMS

1. A porous keratin material for use in the replacement and augmentation of bone.

2. A dense keratin material for use in bone fixation and immobilization.

3. A material according to either claim 1 or 2 wherein the keratin is S-sulfonated.

4. A material according to any one of claims 1-3 wherein the keratin is enriched in intermediate filament protein.

5. The keratin material of claim 4 which is prepared by compression of solid keratin powder.

6. The dense material of claim 3 which is prepared by compression of keratin film.

7. The material of any one of claims 1-6 that contains up to 60% calcium salts.

8. The material of any one of claims 5 to 7 wherein compression is followed by freeze-drying of solid keratin.

9. A use of a dense keratin material in the manufacture of a medical support or scaffold in the preservation, restoration and development of form and function of bone.

10. The use according to claim 9 wherein the keratin material is S-sulfonated.

11. The use according to claim 9 or 10 wherein the keratin is enriched in intermediate filament protein.

12. A method of forming a dense material of S-sulfonated keratin material into an orthopaedic product comprising:
    a) compressing keratin in the presence of heat and water;
    b) strengthening the material;
    c) washing the material to remove residual chemicals; and

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d) drying the material.

13. A method for forming a dense material of S-sulfonated keratin into an orthopaedic product comprising:

a) strengthening the keratin-containing starting material;
b) washing the material to remove residual chemicals;
c) drying the material; and
d) compressing keratin in the presence of heat and water.

14. A method of forming a porous S-sufonated enriched keratin material comprising:

a) compressing keratin in the presence of a soluble compound;
b) removing and strengthening the material;
c) washing the protein material; and
d) freeze drying the material.

15. A method according to claim 14 wherein the soluble compound is selected from sodium chloride or another biocompatible salt, or glycerol or another biocompatible solvent.

16. A method according to any one of claims 14-15 wherein the amount and nature of soluble compound is controlled to select the pore sizes and allow the infiltration of osteoprogenitor cells to facilitate the colonization of keratin material when implanted.

17. A method according to any of claims 12-16 further including the addition of hydroxyapatite to the keratin starting material.

18. A method according to any one of claims 12-17 wherein the keratin is enriched in intermediate filament protein.

19. A keratin material prepared by the method of any one of claims 12-18.

20. A biocompatible material in the form of a porous keratin that is enriched in intermediate filament protein for use in bone replacement / augmentation therapy.

21. A biocompatible material according to claim 20 wherein the keratin is S-sulfonated.

22. A biocompatible material according to claim 20 or 21 which contains up to 60% calcium salts.

23. A biocompatible material according to any one of claims 20-22 wherein the material is prepared by compression of solid keratin powder.

24. A biocompatible material according to claim 23 wherein compression is followed by freeze-drying.

25. A biocompatible material according to any one of claims 20-24 wherein the material is prepared from a solution of keratin.

26. A biocompatible material according to claim 25 wherein the solution of keratin is freeze-dried.

27. An orthopaedic medical material manufactured from biocompatible keratin material for treatment of fractures by internal fixation as well as fixation and immobilisation of bone segments.

28. An orthopaedic medical material according to claim 27 which is manufactured from S-sulfonated keratin material.

29. An orthopaedic medical material according to claim 27 or 28 wherein the keratin material is enriched in intermediate filament protein.

30. An orthopaedic medical material according to any one of claims 27-29 prepared by compression of solid keratin powder.

31. An orthopaedic medical material according to any one of claims 27-29 prepared by compression of keratin film.

32. An orthopaedic medical material according to any one of claims 27-29 prepared from a solution of keratin.

33. An orthopaedic medical material according to any one of claims 27-29 that contains up to 60% calcium salts.

34. An orthopaedic medical material according to any one of claims 30-33 wherein the keratin is freeze dried after compression.

35. An orthopaedic material according to any one of claims 27-34 made according to the method of any one of claims 12-18.

36. A method of reforming S-sulfonated keratin enriched in intermediate filament protein into a tough, dense biocompatible material for use as an internal fixation appliance in the treatment of bone fractures.

37. A method according to claim 35 wherein the keratin is enriched in intermediate filament protein.

38. A method according to claim 36 that includes compressing the biocompatible protein in the presence of moisture and chemicals.

39. A method according to claim 38 wherein heat is also used to form a desired shape.

40. A method according to any one of claims 36-39 that also involves the controlled use of reducing agents to remove the sulfonate group from the S-sulfonated keratin and reform the disulfides originally present in the native keratin.

41. A biocompatible keratin enriched material when produced according to any one of claims 36-40.

42. An orthopaedic material according to claim 27 wherein the material is a plate, pin or screw.